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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,817	09/26/2000	Joseph R. Byrum	38-21(51469)B	5384

7590 05/06/2004

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EXAMINER	
MEHTA, ASHWIN D	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/669,817	BYRUM ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *3-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9262000*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-2 and SEQ ID NO: 4 the paper submitted April 1, 2004 is acknowledged. The traversal is on the ground(s) that Applicants argue that the Examiner has not shown that a search and examination of the entire application would be a serious burden. Applicants argue that Group I and I are related to nucleic acids and encoded proteins (response, page 2, 1st and 2nd full paragraphs). This is not found persuasive because searches of proteins encoded by the product of Group I would not necessarily reveal any information about the nucleic acid molecule of Group I. Further, the application contains 43,701 sequences, the search and examination for which would obviously be a rather serious burden. Applicants argue that no serious burden would arise from search and examination of at least 10 nucleotide sequences (response, page 2, 2nd full paragraph). However, searches of more than a single sequence per application currently does place a burden on the Office's automated searching capabilities.

The requirement is still deemed proper and is therefore made FINAL. Claims 1 and 2 are examined in this Office action. Claims 3-9 and SEQ ID NOs: 1-3 and 5-43,701 are withdrawn from consideration as being drawn to non-elected inventions.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, for example on page 5, lines 9, 10, and 12, and page 27, lines

25-26. Applicant is required to delete these and any other embedded hyperlinks and/or other forms of browser-executable codes. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well-established utility.

The claims are drawn towards any substantially purified nucleic acid molecule that encodes any plant protein or fragment thereof comprising a nucleic acid sequence from SEQ ID NO: 4; or wherein said plant protein is a rice protein.

The specification discloses 43,701 nucleic acid sequences that are EST nucleic acid molecules (page 16, lines 1-6, sequence listing). The nucleic acid sequences were derived from rice cDNA libraries (page 33, lines 4-7; Example 1, pages 84-87). Here, the nucleic acid sequence of SEQ ID NO: 4 is the elected invention. The specification indicates that the disclosed ESTs can be used to acquire genes whose encoded proteins are involved in various plant processes (page 33, lines 4-26), or acquire promoters or cis-regulatory elements, or to generally obtain nucleic acid molecules from other organisms (page 34, line 1 to page 35, line 10). No particular use is disclosed for any of putative protein encoded by SEQ ID NO: 4.

The claimed nucleic acid molecule is not supported by a specific asserted utility because the disclosed use of the nucleic acid is generally applicable to any nucleic acid and therefore is not particular to the claimed molecule. Further, the claimed cDNA compound is not supported

by a substantially utility because the specification states only that the EST is useful as a probe or primer in isolating other unspecific genes or regulatory regions of genes. Once such a gene is isolated and the protein obtained, further basic research would need to be conducted to characterize it. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins or regulatory regions that are to be produced as final products resulting from processes involving the claimed cDNA have asserted or identified specific and substantial utilities. Identifying and studying the properties of the protein itself or the mechanisms in which the protein or regulatory region is involved does not define a "real world" context of use. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for SEQ ID NO: 4 such that another non-asserted utility would be well established for the compounds.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 2: the recitation, "substantially" in line 1 of both claims renders them indefinite. It is not clear what is meant by this term. When is a nucleic acid molecule considered purified, as opposed to "substantially" purified? The metes and bounds of the claims are unclear.

Further in claim 1: the recitation, "or fragment thereof" in line 2 renders the claim indefinite. It is not clear is the recitation is referring to a fragment of the plant protein, or the nucleic acid molecule.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn towards any substantially purified nucleic acid molecule that encodes any plant protein or fragment thereof comprising a nucleic acid sequence from SEQ ID NO: 4; or wherein said plant protein is a rice protein.

The specification discloses 43,701 nucleic acid sequences that are EST nucleic acid molecules (page 16, lines 1-6, sequence listing). The nucleic acid sequences were derived from rice cDNA libraries (page 33, lines 4-7; Example 1, pages 84-87). Here, the nucleic acid

sequence of SEQ ID NO: 4 is the elected invention. The specification indicates that the disclosed ESTs can be used to acquire genes whose encoded proteins are involved in various plant processes (page 33, lines 4-26), or acquire promoters or cis-regulatory elements, or to generally obtain nucleic acid molecules from other organisms (page 34, line 1 to page 35, line 10). No particular use is disclosed for any of putative protein encoded by SEQ ID NO: 4.

A review of the full content of the specification indicates that SEQ ID NO: 4 is essential to the claimed invention. A review of the language of claim 1 indicates that the claim is drawn to a genus- any substantially purified nucleic acid molecule encoding any plant protein, or fragment thereof, comprising the nucleotide sequence in SEQ ID NO: 4. Dependent claim 2 limits the plant protein to be from rice. A search indicates that the nucleotide sequence set forth in SEQ ID NO: 4 is novel and unobvious.

There is a single species explicitly disclosed- the nucleotide sequence consisting of SEQ ID NO: 4.

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses full-length genes and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO: 4 is only a fragment of a cDNA. When reviewing a claim that encompasses a widely varying genus, common attributes or features shared among species of the genus must be evaluated. In the case of a partial cDNA sequence that is claimed with open language (comprising), the genus encompasses a variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its complete coding region. A partial

cDNA that does not include a disclosure of any complete open reading frame of which it would be a part, is not representative of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule is disclosed. Further, defining the cDNA in functional terms would not suffice in the absence of a disclosure of structural features or elements of a cDNA that would encode a protein having a stated function.

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Col., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Here, the specification discloses only a single common structural feature shared by members of the claimed genus, i.e., SEQ ID NO: 4. Since the claimed genus encompasses genes yet to be discovered, DNA constructs that encode fragments of proteins, etc., the disclosed structural feature does not "constitute a substantial portion" of the claimed genus. Therefore, the disclosure of SEQ ID NO: 4 does not provide an adequate written description of the claimed genus.

Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO: 4, 2) the breadth of the claims as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs, 3) he lack of correlation between the structure and function of the genes and/or fusion constructs; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicants were in possession of the genus of substantially purified nucleic acid molecules which comprise SEQ ID NO: 4.

6. Claims 1 and 2 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Further, as SEQ ID NO: 4 is a partial cDNA sequence and does not encode a complete protein. The nucleotide sequence of SEQ ID NO: 4 is not predictive of the remaining sequences of the complete cDNA. As the function of the claimed nucleic acid molecule, or the protein it encodes, is not taught, one skilled in the art therefore would not know how to use it. Undue experimentation would be required by one skilled in the art to determine the remaining nucleotide sequences of the coding region that SEQ ID NO: 4 is a part of, and characterize the function of the encoded product. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Also see In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof. Given the breadth of the claims, unpredictability of the art

and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

7. Claims 1-2 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 30, 2004

Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638